

Fw: Review of ATSDR chemical specific consultation: sulfolane
Brandon Perkins
to:
Marcia Bailey
12/28/2010 12:42 PM
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History: This message has been replied to and forwarded.

Marcia

Here is the ATSDR sulfolane consultation. Below there are a number of questions ATSDR is seeking comments on.

Brandon Perkins
Office of Environmental Cleanup
U.S. Environmental Protection Agency, Region 10
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----- Forwarded by Brandon Perkins/R10/USEPA/US on 12/28/2010 12:40 PM

From: "Durant, James T. (ATSDR/DTEM/PRMSB)" <hzd3@cdc.gov>
To: Brandon Perkins/R10/USEPA/US@EPA
Cc: "Holler, James S. (Jim) (ATSDR/DTEM/PRMSB)" <jsh2@CDC.GOV>, "Chou, Selene (ATSDR/DTEM/PRMSB)" <cjc3@CDC.GOV>, "Nickle, Richard (ATSDR/DTEM/PRMSB)" <ran2@CDC.GOV>, "Kauffman, Richard (ATSDR/DRO)" <rxk3@cdc.gov>
Date: 12/22/2010 11:29 AM
Subject: Review of ATSDR chemical specific consultation: sulfolane

ATSDR would like to thank you for agreeing to review of the chemical specific health consultation on sulfolane. On background, in 2009, ATSDR was asked by the Alaska Department of Health and Social Services to derive a provisional health guidance value (public health action level) for the chemical, sulfolane. After release of our initial health consultation in February 2010, a consulting firm for the potentially responsible party, ToxStrategies, presented ATSDR with a previously unpublished study of sulfolane in rats that was conducted at Huntington Life Sciences in the United Kingdom. ToxStrategies also expressed concerns regarding ATSDR's methodology in development of the provisional health guidance values. Specifically, ToxStrategies had expressed concerns about our lack of using appropriate benchmark modeling techniques for the sulfolane data. Because of the technical complexity of the issues ToxStrategies is raising and to ensure that ATSDR's recommendations are scientifically supported, we are asking you to review of the enclosed draft health consultation.
<<ATSDR Sulfolane_review draft.docx>>

The attached draft health consultation re-examines the available data from

both a no/lowest-observed adverse effect level standpoint as well as utilizing the benchmark dose modeling approach to derive a provisional health guidance value for sulfolane. ATSDR would like your review and comment on the following areas:

Question 1. Did ATSDR select the appropriate point of departure in its assessment of sulfolane?

Question 2. Are the methodologies used to establish the provisional health guidance value for sulfolane by ATSDR scientifically sound and sufficiently protective of public health?

Question 3. Is the slope-restricted log logistic BMDS of the Zhu et al. 1987 guinea pig fatty liver degeneration overly anti-conservative?

Question 4: Is the log transformed quantal-linear model Zhu et al. 1987 guinea pig liver data scientifically sound? Is the resulting BMDL preferable to the BMDL from the slope-restricted log logistic model of the same data?

Question 5. Are the health consultation's results presented and interpreted appropriately and completely?

Question 6. Are the health consultation's conclusions and recommendations appropriate and complete?

Question 7. Are there any notable omissions or ambiguities in scientific logic anywhere in the health consultation that would be germane to the evaluation of potential adverse health effects?

Question 8. Are there any other comments on the health consultation?

While ATSDR does not have plans to publish reviewer comments in the document, the identity of the reviewers will be disclosed. Furthermore, your comments may be subject to release to interested parties under applicable laws (e.g. Freedom of Information Act). Your comments will be attributed to you.

In addition to the draft health consultation, please find:

- English translation of Zhu Z, Sun M, Li Z, et al. 1987. An investigation of maximum allowable concentration of sulfolane in surface water. J West China Univ Med Sci 18(4):376-80.

<<sulfolane MAC translated.docx>>

- ToxStrategies. 2010. Assessment of Toxicological Data for Sulfolane - Update II. Austin, TX: ToxStrategies, Inc. August 2010.

<<sulfolane white paper_update_final_Aug 18 2010.pdf>>

- ToxStrategies. 2010. Development of an Oral BMD for Sulfolane based on data from a 90 Day Drinking Water Study Conducted by Huntington Life Science (2001). Austin, TX: ToxStrategies, Inc. August 2010.

<<HLS Summary-final_Aug 18 2010.pdf>>

We will transmit an electronic copy of the Huntington Life Sciences study on request as it is exhaustive in length. If you have any questions please

do not hesitate to contact me at 770.488.3358

Sincerely,

/s/

James Holler

Acting Division Director

Division of Toxicology and Environmental Medicine

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